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*Implantable system to treat detrusor-hyperreflexia.*

## **Patent implantable system to treat detrusor-hyperreflexia.**

23 okt 98

The patent is about an implantable system to treat detrusor-hyperreflexia (DH).

DH will develop in all patient with spinal cord injury and in a large portion of the patients with neurological diseases such as multiple sclerosis. DH is characterized by involuntary detrusor contractions during bladder filling at relative small volumes. The contractions cannot be suppressed consciously and cause an increase in intravesical pressure of more than 15 cm H<sub>2</sub>O. DH causes a low storage capacity and transient high intravesical pressures resulting in incontinence, risk for kidney damage and bladder hypertrophy.

The neurophysiological basis for detrusor hyperreflexia following spinal cord injury is that the reflex pathways (concerning the bladder) in intact and chronic spinal patients differ. Therefore the voiding reflex (bladder contraction) occurs already at a low filling volume. The impaired storage function could in principle be improved by methods that decrease the sensitivity of the bladder afferents, decrease the activity in the bladder efferents or surgically increase the bladder capacity. Available treatment options are surgical augmentation of the bladder, surgical deafferentation of the bladder and the use of anticholinergic drugs.

What we will attempt is to abort a hyperreflexic contraction automatically. The system will consist of a sensor to detect a hyperreflexic contraction and a stimulator that in turn, will activate and inhibitory reflex by stimulating either the dorsal penile/clitoris nerve or anorectal branches.



The system will consist of the following parts:

1. Electrodes to detect hyperreflexic contraction.
2. Processing unit which amplifies and filters the neural signal and generates an output signal that represents the onset of an hyperreflexic contraction.
3. Stimulator unit which generates a pulse train
4. Electrodes to interface with the sensory nerves to activate an inhibitory reflex.

### **1. Sensing electrodes**

These electrode could be either conventional tripolar cuff electrodes or longitudinal intrafascicular wire electrodes [Lefurge et al., 1991].

The electrodes need to pick up a neural signal from either the efferent nerve fibers (motor) innervating the detrusor muscle or the afferent nerve fibers (sensory) innervating the bladder wall. The relevant nerves for these electrodes are therefore the pelvic nerve (containing both afferent and efferent fibers), extradural sacral nerve roots (both afferent and efferent), intradural ventral sacral nerve root (efferent fibers) and the dorsal sacral nerve roots (afferent fibers). However the more distal the recording electrode will be placed the more selective the recorded signal will be (no contamination from signals coming from other organs).

Electrodes placed on afferent could in principle also be used to relay information about the bladder volume.

## **2. Processing unit**

The recorded signal need to be processed and interpreted. Therefore it needs to be amplified and filtered. In addition a feature of the signal needs to be extracted that represents the onset of a hyperreflexic contraction. This could be as simple as setting a threshold in the signal.

## **3. Stimulator**

The stimulator generates, in response to a trigger signal that it receives from the processing unit, a train of stimulation pulses. These pulses should activate an inhibitory reflex which will arrest an ongoing contraction. The following parameters of the pulse train should be adjustable: length of the pulse train (1-60 s), pulse rate (1-20 pulses/s), pulse amplitude (0-5 mA) pulse duration (10-200 us).

## **4. Stimulation electrodes**

These electrodes to interface with the sensory nerves to activate an inhibitory reflex. In principle one wants to activate the reflex without activation other systems. This leads to the following 2 nerves which seem suitable to induce sufficient inhibition: 1) dorsal clitoral or penile branch of the pudendal nerve and 2) anorectal branches of the pelvic nerves. [Lindström and Sudsuang, 1989]

These electrodes could be cuff electrodes but could also be little wire electrodes sewn onto the nerve.

## **References**

T. Lefurge, E. Goodall, K. Horsch, L. Stensaas, and A. Schoenberg, "Chronically implanted intrafascicular recording electrodes," *Annals of Biomed. Eng.*, vol. 19, pp. 197-207, 1991.

S. Lindström and R. Sudsuang, "Functionally specific bladder reflexes from pelvic and pudendal nerve branches; an experimental study in the cat," *Neurourol. Urodyn*, vol. 8, pp. 392-393, 1989.

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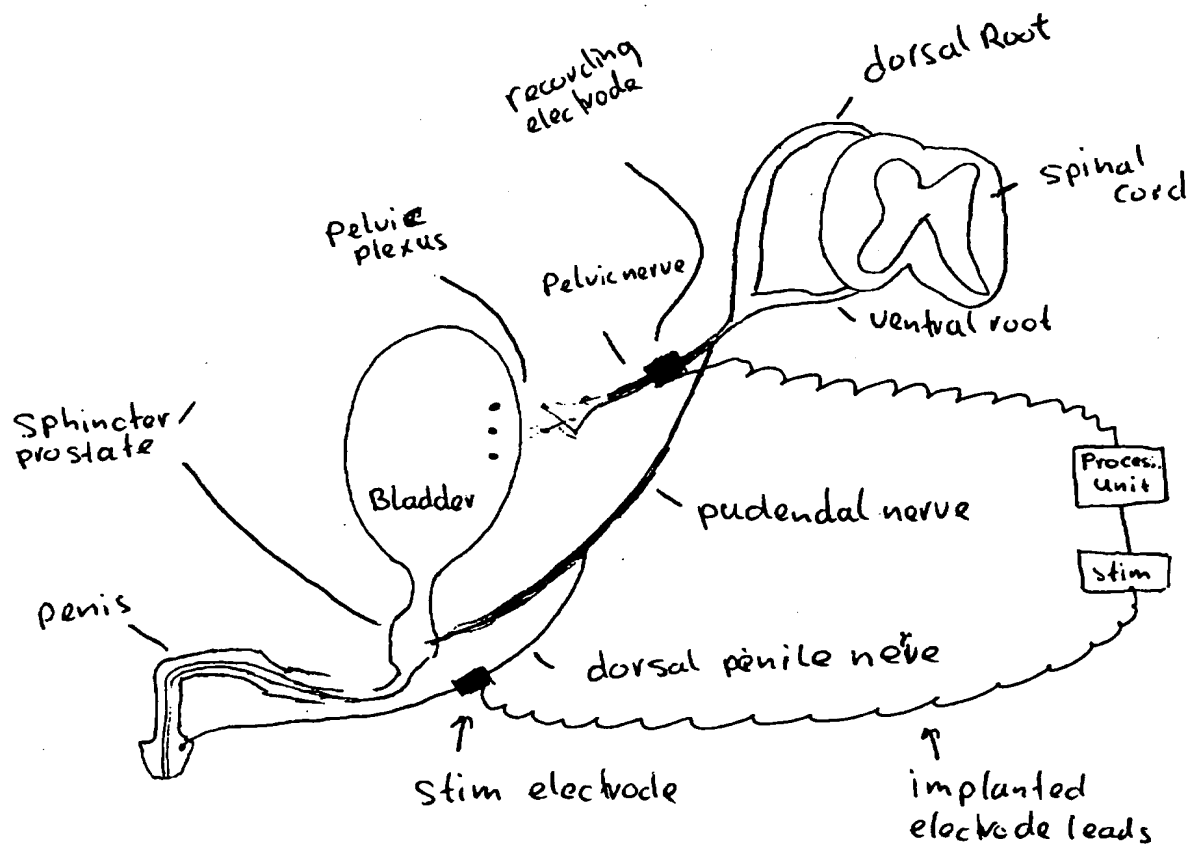
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